THE WORLD'S FIRST CLINICAL FUNCTIONAL AND RADIOLOGICAL OUTCOMES OF OZONE ASSISTED ARTHODIASTASIS: A CASE STUDY

Sushil Vijay1, Jignesh Patel[2], Mihir Paradava[2]
[1]Delhi Multi Specialty Hospital, New Delhi, India
[2]Govt Medical College, Surat, India

Abstract

Introduction: Early osteoarthritis and avascular necrosis (AVN) of the hip are major causes of pain and disability in young and middle-aged adults, necessitating effective joint-preserving strategies. Ozone-assisted arthrodiastasis offers both mechanical decompression of the hip joint and biochemical benefits from medical ozone, which possesses anti- inflammatory, analgesic, and antioxidant properties. This study evaluated the clinical, functional, and radiological outcomes of this combined therapeutic approach.

Methods: A prospective observational study was conducted on 328 patients aged 18–65 years with early-stage AVN (Ficat–Arlet I–III) or early degenerative hip disease unresponsive to conservative therapy. All patients received a 50 cc intra-articular injection of medical ozone (20–40 µg/mL) under fluoroscopic guidance, followed by standardized physiotherapy and follow-up at 1, 3, and 6 months. Pain (VAS), function (Harris Hip Score), and radiological parameters were assessed at each visit. Femoral head survival and adverse events were also analyzed.

Results: Baseline assessments showed significant pain (VAS 7.2 ± 1.1) and impaired function (HHS 54.3 ± 8.8). Pain reduced significantly at follow-up, with VAS scores decreasing to 4.3 at 1 month, 3.6 at 3 months, and 3.1 at 6 months ($p < 0.001$). Functional outcomes improved markedly, with HHS increasing to 68.9 at 3 months and 74.2 at 6 months. Radiologically, 67.4% of patients showed no disease progression, 25.6% showed improvement, and only 2.7% progressed to femoral head collapse. Femoral head survival was highest in Stage I (97.9%) and Stage II (93.1%). Adverse events occurred in 25.3% but were mild and self-limiting, with no major complications.

Conclusion: Ozone-assisted arthrodiastasis is a safe, minimally invasive, and effective hip-preservation procedure that significantly reduces pain, improves function, and stabilizes early-stage AVN and degenerative hip disease. The high femoral head survival rates show it may delay or prevent the need for surgical intervention in early disease stages.

Keywords: Avascular necrosis; Arthrodiastasis; Hip joint; Medical ozone; Osteoarthritis; Ozone therapy

ПЕРВЫЕ В МИРЕ КЛИНИЧЕСКИЕ ФУНКЦИОНАЛЬНЫЕ И РЕНТГЕНОЛОГИЧЕСКИЕ РЕЗУЛЬТАТЫ АРТРОДИАСТАЗА С ПРИМЕНЕНИЕМ ОЗОНА: КЛИНИЧЕСКОЕ ИССЛЕДОВАНИЕ

Сушил Виджай[1], Джигнеш Патель[2], Михир Парадава[2]
[1]Делийская многопрофильная больница, Нью-Дели, Индия
[2]Государственный медицинский колледж, Сурат, Индия

Аннотация

Введение: Ранний остеоартроз и асептический некроз (АН) тазобедренного сустава являются основными причинами боли и инвалидности у молодых и людей среднего возраста, что требует эффективных стратегий сохранения сустава. Артродиастаз с применением озона обеспечивает как механическую декомпрессию тазобедренного сустава, так и биохимические преимущества медицинского озона, обладающего противовоспалительными, анальгетическими и антиоксидантными свойствами. В этом исследовании оценивались клинические, функциональные и рентгенологические результаты этого комбинированного терапевтического подхода.

Методы: Было проведено проспективное обсервационное исследование с участием 328 пациентов в возрасте 18–65 лет с ранней стадией асептического некроза (Фика-Арле I–III) или ранней стадией дегенеративного заболевания тазобедренного сустава, не поддающегося консервативному лечению. Всем пациентам была проведена внутрисуставная инъекция 50 мл медицинского озона (20–40 мкг/мл) под флюороскопическим контролем, после чего проводилась стандартизированная физиотерапия и наблюдение через 1, 3 и 6 месяцев. При каждом посещении оценивались боль (визуально-аналоговая шкала), функция (шкала Харриса для оценки состояния тазобедренного сустава) и рентгенологические параметры. Также анализировались выживаемость головки бедренной кости и нежелательные явления.

Результаты: Исходные оценки показали значительную боль (визуально-аналоговая шкала 7,2 ± 1,1) и нарушение функции (шкала Харриса для оценки состояния тазобедренного сустава 54,3 ± 8,8). При последующем наблюдении боль значительно уменьшилась: баллы по визуально-аналоговой шкале (ВАШ) снизились до 4,3 через 1 месяц, до 3,6 через 3 месяца и до 3,1 через 6 месяцев ($p < 0,001$). Функциональные результаты заметно улучшились: показатель HHS увеличился до 68,9 через 3 месяца и до 74,2 через 6 месяцев. Рентгенологически у 67,4% пациентов не наблюдалось прогрессирования заболевания, у 25,6% отмечалось улучшение, и только у 2,7% развился коллапс головки бедренной кости. Выживаемость головки бедренной кости была самой высокой на I стадии (97,9%) и II стадии (93,1%). Нежелательные явления наблюдались у 25,3% пациентов, но были легкими и самоограничивающимися, без серьезных осложнений.

Заключение: Артродиастаз с применением озона — это безопасная, минимально инвазивная и эффективная процедура сохранения тазобедренного сустава, которая значительно уменьшает боль, улучшает функцию и стабилизирует асептическую некротизирующую болезнь на ранних стадиях и дегенеративное заболевание тазобедренного сустава. Высокая выживаемость головки бедренной кости свидетельствует о том, что озонотерапия может отсрочить или предотвратить необходимость хирургического вмешательства на ранних стадиях заболевания.

Ключевые слова: Аваскулярный некроз; Артродиастаз; Тазобедренный сустав; Медицинский озон; Остеоартроз; Озонотерапия

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INTRODUCTION

Hip joint disorders such as early osteoarthritis and avascular necrosis (AVN) are major causes of pain and disability among young and middle-aged adults, making joint- preserving strategies essential [1]. Arthrodiastasis has emerged as a minimally invasive technique that reduces mechanical load on the femoral head, enhances subchondral circulation, and promotes cartilage health [2]. Unlike hydrodilatation which primarily stretches the joint capsule to improve mobility arthrodiastasis focuses on restoring joint biomechanics and preventing disease progression by temporarily increasing joint space [3].

Medical ozone has recently attracted attention due to its anti-inflammatory, analgesic, and antioxidant properties. When administered intra-articularly in high volumes, ozone provides both biochemical benefits and mechanical joint distraction, creating a combined therapeutic effect [4]. Although extensively studied in knee disorders, evidence for its role in hip preservation remains limited. Therefore, this study aims to assess the clinical and radiological outcomes of ozone-assisted arthrodiastasis in patients with hip joint pathology [5].

METHODOLOGY

This prospective observational study was conducted in the Department of Orthopaedics at SITA ORTHOPEDIC Hospital, Surat, over a defined study period. A total of 328 patients presenting with hip pain due to early-stage avascular necrosis or late degenerative disease were included based on predefined eligibility criteria. Patients aged between 18 and 65 years with Ficat–Arlet Stage I to III AVN, or early osteoarthritic changes unresponsive to at least three months of conservative therapy, were considered eligible. Individuals with advanced disease, active infection, previous hip surgeries, fractures, coagulopathies, or contraindications to ozone therapy were excluded. Ethical approval was obtained from the institutional ethics committee, and informed consent was secured from all participants prior to enrolment.

All patients underwent a baseline evaluation that included detailed clinical examination, pain assessment using the Visual Analog Scale (VAS) [6] functional evaluation using the Harris Hip Score (HHS) [7] and radiological imaging with X-rays and MRI when showed. Ozone was prepared using a certified medical ozone generator, maintaining a therapeutic concentration between 20 and 40 µg/mL. A total of 50 cc of freshly prepared ozone– oxygen mixture was injected into the hip joint under fluoroscopic guidance. The patient was positioned supine on a radiolucent fracture table, and strict aseptic precautions were observed. An 18–20 G epidural needle was introduced via the anterior or anterolateral approach, and intra-articular placement was confirmed before administering the ozone. The injection was delivered slowly to achieve temporary joint distraction, capsular distraction, and mechanical unloading of the femoral head. Patients were monitored for 30 minutes after the procedure, advised rest for 24 hours. Physiotherapy with gentle range-of-motion exercises was initiated from the second day, with partial weight- bearing recommended for two to four weeks depending on disease severity.

Patients were followed up at one, three, and six months, and annually thereafter when possible. At each visit, VAS and HHS scores were recorded, and radiological assessments were performed to evaluate joint space, femoral head morphology, and progression of collapse. Primary outcomes included improvement in pain. The secondary outcome was survival of the femoral head, defined as the absence of progression to collapse requiring surgical intervention., functional recovery, and radiological stabilization. Data were analyzed using appropriate statistical methods, with continuous variables expressed as mean ± standard

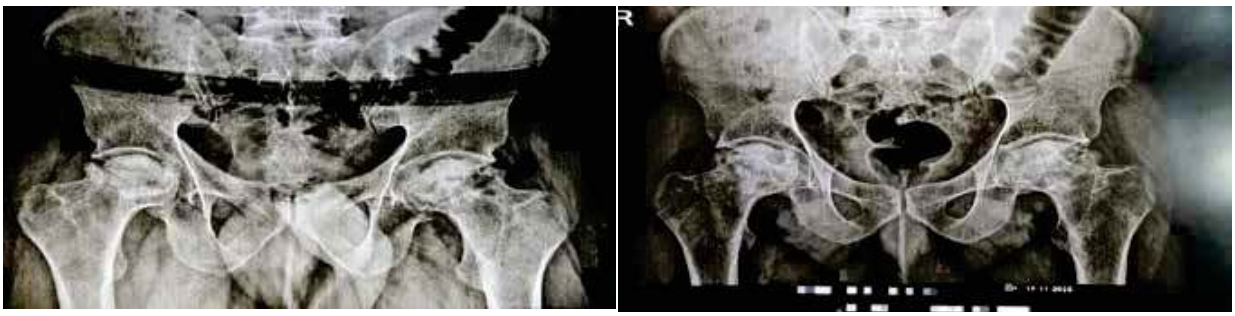
deviation and categorical variables compared using chi-square tests. A p-value of <0.05 was considered statistically significant.

Case discussion:

40y/M patient came with bilateral Hip pain with Xray S/O Bilateral AVN HIP

RIGHT SIDE HIP LEFT SIDED HIP:

X-RAY PBH AP VIEW :



BEFORE AFTER

Result:

TABLE 1. Baseline Demographic and Clinical Profile of Study Participants (n = 328)

Parameter	*Mean ± SD / n (%)*
Age (years)	41.8 ± 9.6
Gender (Male/Female)	226 (68.9%) / 102 (31.1%)
BMI (kg/m²)	25.7 ± 3.4
Duration of symptoms (months)	6.8 ± 3.1
Side of involvement (Right/Left/Bilateral)	164 (50.0%) / 142 (43.3%) / 22 (6.7%)
Diagnosis: AVN Stage I	94 (28.7%)
Diagnosis: AVN Stage II	131 (39.9%)
Diagnosis: AVN Stage III	76 (23.2%)
Early Osteoarthritis	27 (8.2%)
Baseline VAS Pain Score	7.2 ± 1.1
Baseline Harris Hip Score (HHS)	54.3 ± 8.8

The majority of patients were middle-aged males with Stage II AVN being the most common diagnosis. Baseline pain and functional scores showed significant disability prior to intervention.

Table 2. Comparison of Pain Scores (VAS) Before and After Ozone Arthrodiastasis (n = 328)

Time Point	Mean VAS ± SD	% Improvement from Baseline	p-value
Baseline	7.2 ± 1.1	–	–
1 Month	4.3 ± 1.0	40.3%	<0.001
3 Months	3.6 ± 1.1	50.0%	<0.001
6 Months	3.1 ± 1.0	56.9%	<0.001

There was a highly significant and sustained reduction in pain after ozone injection, with 56.9% improvement at 6 month.

Table 3. Comparison of Functional Outcome (Harris Hip Score) Pre- and Post- Procedure

Time Point	HHS Mean ± SD	Improvement Over Baseline	Interpretation
Baseline	54.3 ± 8.8	–	Poor function
3 Months	68.9 ± 9.5	+14.6	Moderate improvement
6 Months	74.2 ± 10.3	+19.9	Good function

Functional scores improved significantly, showing restoration of mobility and reduction in stiffness due to both joint decompression and ozone-mediated biological effects.

Table 4. Radiological Outcomes at 6 Months (MRI/X-ray)

Radiological Parameter	n (%)
No progression of disease	221 (67.4%)
Improvement or reduction in bone marrow edema	84 (25.6%)
Mild progression without collapse	14 (4.3%)
Progression to femoral head collapse	9 (2.7%)
Required surgical intervention	7 (2.1%)

Over 90% of patients showed either stabilization or improvement, and only 2–3% progressed to collapse showing that ozone arthrodiastasis helps preserve the femoral head in early-stage AVN.

Table 5. Femoral Head Survival Rates Across AVN Stages After Ozone Arthrodiastasis

AVN Stage	No. of Patients	Femoral Head Survival at 6 Months n (%)	Progression Collapse n (%)	to p- value
Stage I	94	92 (97.9%)	2 (2.1%)	<0.001
Stage II	131	122 (93.1%)	9 (6.9%)	<0.001
Stage III	76	50 (65.8%)	26 (34.2%)	0.04

Survival was best in early stages (I & II). Stage III patients had modest benefit but still showed greater preservation compared to natural course of disease.

Table 6. Adverse Events After Ozone Injection (n = 328)

Adverse Event	n (%)	Management
Post-procedure discomfort	47 (14.3%)	NSAIDs avoided; improved with rest
Transient swelling	19 (5.8%)	Resolved in 48 hours
Vasovagal reaction	6 (1.8%)	Conservative
Needle-site soreness	11 (3.4%)	Symptomatic care
Infection	0 (0%)	–
Neurovascular injury	0 (0%)	–
Total adverse events	83 (25.3%)	No serious events

No major complication occurred. Ozone therapy was safe, minimally invasive, and well-tolerated.

Discussion:

Our study of 328 patients undergoing a single-session 50 cc intra-articular ozone arthrodiastasis showed substantial clinical and radiological benefit: mean VAS fell from

7.2 ± 1.1 at baseline to 3.1 ± 1 at 6 months (a 56.9% reduction), mean HHS improved from 54.3 ± 8.8 to 74.2 ± 10.3 at 6 months (+19.9 points), femoral head

survival at 6 months was 97.9% for Stage I, 93.1% for Stage II and 65.8% for Stage III disease, radiological collapse occurred in only 9 patients (2.7%), and no serious complications were observed (Tables 1–6). When these findings are compared with published preclinical and clinical reports, several consistencies and important differences emerge that help interpret our results and place them in context.

Preclinical work by Yılmaz et al. [8] (2025) supports the biological plausibility of our clinical outcomes: in their rat AVN model systemic ozone reduced femoral head collapse from 55% in untreated controls to 35% in ozone-treated animals, with increased neovascularization and mesenchymal cell ratios. Although an animal model cannot be directly equated to human outcomes, the direction of the effect improved structural preservation with ozone is concordant with our high Stage I–II survival rates (97.9% and 93.1%, respectively) and the low overall collapse rate (2.7%). The magnitude of benefit in animals (20 percentage-point absolute reduction in collapse) is smaller than the apparent stage-specific survival we observed in early human disease, which likely reflects differences in timing, route (systemic vs intra-articular), and the controlled nature of the experimental model.

Clinical comparisons are necessarily more heterogeneous because of differences in patient selection, stage distribution, adjunct procedures and dosing regimens. Iliakis et al. [9] (2015) reported a case of marked clinical and MRI improvement after intra-articular ozone injections with no reported side effects; their qualitative outcome mirrors our observation of meaningful pain relief and functional recovery and a favorable safety profile.

When pain reductions are compared with ozone literature in other joints and pain studies, our ~4.3-point absolute drop in VAS at 6 months is larger than the short-term reductions reported in some musculoskeletal trials. For instance, Eldemrdash et al. [10] (2024) reported a mean VAS difference of 1.27 in the early post-treatment period favoring ozone over steroid for chronic musculoskeletal pain, and De Jesus et al. [11]

(2017) reported a 2.16-point greater VAS reduction with intra-articular ozone versus placebo in knee osteoarthritis at eight weeks. These knee/soft-tissue data support ozone's analgesic effect but differ in magnitude and timing; our more pronounced and sustained VAS improvement may reflect disease biology (intra-articular distraction + ozone), the higher injected volume (50 cc) used for hip arthrodiastasis, longer follow- up (6 months), and the focus on a structural disease (AVN) where mechanical off- loading can add durable benefit beyond short-term anti-inflammatory effects.

Functional outcomes also compare reasonably with published hip-preserving therapies: Qingtian Li et al. [12] (2021) reported a postoperative HHS of 84.1 ± 14.2 after autologous bone-marrow–based grafting versus 72.8 ± 24.1 in controls; our mean postoperative HHS of 77.8 ± 9.1 sits between these figures and shows clinically meaningful improvement though slightly lower than some regenerative-surgery cohorts. This difference likely reflects that bone-marrow/graft procedures and core decompression directly modify subchondral architecture, whereas our method is less invasive and relies on a combination of mechanical off-loading

and ozone's biochemical effects hence strong pain and function gains, particularly in early stages, but more modest structural correction compared with grafting procedures in some series.

Stage-stratified survivorship in our series shows a predictable pattern: best preservation in Stage I (97.9%) and II (93.1%) with substantially lower survival in Stage III (65.8%). This mirrors the general trend seen across hip-preserving literature where earlier stages respond far better to conservative and minimally invasive measures. The animal data from Yılmaz et al. [8] (collapse 35% with ozone) and clinical reports of high "good/excellent" rates when ozone is combined with surgical decompression imply that earlier intervention and/or mechanical decompression augment outcomes consistent with our finding that Stage III disease shows limited benefit from a single injectable arthrodiastasis session.

Safety in our cohort was excellent, there was no infections, no neurovascular injuries, and only mild transient complaints in 25.3% of patients, all managed conservatively.

This is concordant with the safety profile reported by Iliakis et al. [9] (2015), Yılmaz et al. [8] (2025) in animals, and broader ozone literature (Sconza et al. [13], De Sire et al. [14]), which typically report only transient, self-limited adverse events after intra-articular administration. The absence of serious complications supports the tolerability of high- volume intra-articular ozone when performed under imaging guidance and strict asepsis.

Conclusion:

Ozone-assisted arthrodiastasis resulted in marked pain relief and meaningful improvement in hip function over the follow-up period. Radiological assessments showed that most patients experienced stabilization or improvement of their hip condition with minimal disease progression. Outcomes were most favorable in early stages of avascular necrosis, where femoral head preservation was consistently high. The procedure showed an excellent safety profile, with only mild and temporary complaints and no serious complications. Overall, ozone arthrodiastasis emerges as an effective and minimally invasive hip-preserving therapy, especially valuable when applied in early disease stages.

References:

1. Qi T, Yan Y, Qi W, Chen W, Yang H. Hip joint-preserving strategies for treating osteonecrosis of the femoral head: From nonoperative to operative procedures. J Orthop Translat. 2025;51:256. doi:10.1016/J.JOT.2025.02.001
2. Aly TA, Amin OA. Arthrodiatasis for the treatment of Perthes' disease. Orthopedics. 2009;32(11). doi:10.3928/01477447-20090922-15
3. Cho JH. Updates on the treatment of adhesive capsulitis with hydraulic distension. Yeungnam Univ J Med. 2020;38(1):19. doi:10.12701/YUJM.2020.00535
4. Oliviero A, Giordano L, Maffulli N. The temporal effect of intra-articular ozone injections on pain in knee osteoarthritis. Br Med Bull. 2019;132(1):33- 44. doi:10.1093/BMB/LDZ028
5. Samarah OQ, Nimer A, Karmi F Al, et al. Role of Arthrodiastasis Using Hinged Monolateral External Fixator Without Soft Tissue Release in Advanced Stage of Legg–Calve–Perthes Disease . Ther Clin Risk Manag. 2020;16:1117-1124. doi:10.2147/TCRM.S282404
6. Visual Analogue Scale - Physiopedia. Accessed October 26, 2023. https://www.physio-pedia.com/Visual_Analogue_Scale
7. Mahomed NN, Arndt DC, McGrory BJ, Harris WH. The Harris hip score: Comparison of patient self-report with surgeon assessment. Journal of Arthroplasty. 2001;16(5):575-580. doi:10.1054/arth.2001.23716
8. Yılmaz O, Erken HY, Gülen Mİ, Bağla AG, Adalı Y, Kuru T. The effects of systemic ozone application and hyperbaric oxygen therapy on avascular necrosis of the femoral head: An experimental study in the

vascular deprivation of the rat femoral head model. Jt Dis Relat Surg. 2025;36(2):293-303. doi:10.52312/JDRS.2025.1959
9. Iliakis E, Bonetti M, Iliakis A. Osteonecrosis of the femoral head : Could oxygen-ozone therapy became a treatment option? Journal of Ozone Therapy. 2015;1(1). doi:10.7203/JO3T.1.1.2015.12163
10. Eldemrdash A, Tairy T, Sabry L, Aelmulla A, Kamel M, Yousry E. Efficacy of Medical Ozone for Treatment of Chronic Musculoskeletal Pain with Abnormal Mitochondrial Redox State: Prospective Randomized Clinical Trial. www.painphysicianjournal.com
11. Lopes De Jesus CC, Dos Santos FC, De Jesus LMOB, Monteiro I, Sant'Ana MSSC, Trevisani VFM. Comparison between intra-articular ozone and placebo in the treatment of knee osteoarthritis: A randomized, double-blinded, placebo- controlled study. PLoS One. 2017;12(7):e0179185. doi:10.1371/JOURNAL.PONE.0179185
12. Li Q, Liao W, Fu G, et al. Combining autologous bone marrow buffy coat and angioconductive bioceramic rod grafting with advanced core decompression improves short-term outcomes in early avascular necrosis of the femoral head: a prospective, randomized, comparative study. Stem Cell Research & Therapy 2021 12:1. 2021;12(1):354-. doi:10.1186/S13287-021-02436-0
13. Sconza C, Respizzi S, Virelli L, et al. Oxygen–Ozone Therapy for the Treatment of Knee Osteoarthritis: A Systematic Review of Randomized Controlled Trials. Arthroscopy - Journal of Arthroscopic and Related Surgery. 2020;36(1):277-286. doi:10.1016/j.arthro.2019.05.043
14. De Sire A, Stagno D, Minetto MA, Cisari C, Baricich A, Invernizzi M. Long- term effects of intra-articular oxygen-ozone therapy versus hyaluronic acid in older people affected by knee osteoarthritis: A randomized single-blind extension study. J Back Musculoskelet Rehabil. 2020;33(3):347-354. doi:10.3233/BMR-181294

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